

Appl. No. : 10/719,532
Filed : November 21, 2003

REMARKS

The claim amendments and remarks herein are responsive to the Office Action dated March 19, 2007.

Claim Objections

The Examiner objected to the use of “the method of claim 3” in Claim 6. Applicant has canceled Claim 6. Accordingly, Applicant respectfully requests withdrawal of the claim objection.

Claim Rejections Under 35 USC § 112 – Second Paragraph

The Examiner rejected Claim 6 as being indefinite because the claims refer to “*Dicrocoelium dendriticum*”. Applicant has amended the relevant claims to correct the typographical error. Applicant has also amended the specification.

The Examiner rejected Claim 8 as being indefinite for reciting “wherein said protein is a recombinant cell.” Applicant has amended Claim 8 to clarify that “said protein is recombinant.”

In view of the above amendments, Applicant respectfully requests that the Examiner withdraw the rejection of Claim 8 under 35 USC § 112.

Claim Rejections Under 35 U.S.C. § 112 – first paragraph: Written Description & Enablement

The Examiner rejected Claims 1-6, 8, and 11-12 as failing to comply with the written description and enablement requirements. Applicant has canceled Claims 3-6 and amended Claims 1, 8, and 12.

Although Applicant respectfully disagrees with the Examiner’s characterization that the claims are not enabled. However, in an effort to expedite prosecution, Applicant has amended the rejected claims as follows:

- Applicant has deleted the term “to prevent” in Claims 1 and 12;
- Applicant has amended the term helminthic *agent* to recite a helminthic *antigen* in Claim 1;
- Applicant has deleted the term “vaccine” in Claim 12; and

Appl. No. : 10/719,532
Filed : November 21, 2003

- Applicant has amended Claim 1 to recite a *helminth-based antigen comprises a protein obtained or derived from a species selected from the group consisting of one or more of the following: Capillaria hepatica and Dicrocoelium dendriticum*, thereby overcoming the Examiner's concern that “[t]he claims encompass many helminth antigens that would not work.” OA at page 7.

Finally, the Examiner states that there is “no data to enable the claims.” OA at page 5. Applicant believes that the Examiner’s request for data was based on the breadth of the previously presented claims. In view of the amendments identified above, Applicant asserts that the specification provides ample support for the claims. However, any subsequent argument by the Examiner that data is required to support the amended claims would, respectfully, be unfounded. It is well-established that an applicant is not required to submit data to establish enablement. For example, in *Ex Parte Kyle*, the Board of Patent Appeals and Interferences reversed the Examiner’s rejection of claims and explained:

The examiner has not explained why the specification’s straightforward protocols for synthesizing, identifying and using bradykinin antagonists, together with what was known in the art at the time of the invention, does not satisfy the enablement requirement of 35 U.S.C. § 112.

Finally, to the extent that the examiner requires an assurance of certainty (“[t]here is insufficient bioassay data provided ... which teaches that all of the possible Bk analogs would be effective as antagonist,” (Examiner’s Answer, page 3)) to demonstrate enablement, we note that no legal authority has been cited in support of this requirement. On the contrary, a requirement for certainty would be incompatible with any experimentation at all. Accordingly, the rejection of claims 1, 2, 4 and 5 under 35 U.S.C. § 112, first paragraph is reversed.

Ex Parte Kyle, 2000 WL 35451360, *4 (Bd.Pat.App. & Interf.). See also *Carter-Wallace, Inc. v. Riverton Laboratories, Inc.*, 433 F.2d 1034, 1037-1038 (2d Cir. 1970) (emphasizing that “submission of test information to the Patent Office in support of the claims made in an application is not required, unless the asserted utility of a compound is not believable on its face to persons skilled in the art in view of the contemporary knowledge in the art.”). Here, the asserted utility of the claims should not be questioned. Indeed, the Examiner has not rejected any of the claims under § 101 for lack of utility. Moreover, in light of the Examiner’s reliance upon prior art that allegedly anticipates or obviates Applicant’s claimed invention, it would be inconsistent for the Examiner to later allege that the asserted utility of a helminthic antigen for treating allergies or asthma is not believable to persons skilled in the art.

Appl. No. : 10/719,532
Filed : November 21, 2003

In view of the above amendments and remarks, the Applicant respectfully requests that the Examiner withdraw the written description and enablement rejections.

Claim Rejections Over the Prior Art¹

Claim Rejections Under 35 U.S.C. § 102(b): Rejections Over De Macedo et al.; Ferreira et al.; and U.S. Patent No. 5,996,758

The Examiner rejected Claims 1-5 and 11-12 under 35 U.S.C. § 102(b) as being anticipated by *De Macedo et al.* (1980). The Examiner also rejected Claims 1-5 and 11-12 under § 102(b) over *Ferreira et al.* (1994). The Examiner also rejected Claims 1-5, 8, and 11-12 under § 102(b) over U.S. Patent No. 5,996,758.

Claim 6 stands unrejected over the cited art. Applicant has amended Claim 1 to recite the elements of Claim 6. Therefore, the cited art does not anticipate Claim 1, as amended.

Moreover, the cited art fails to render obvious amended Claim 1. The cited art fails to teach or suggest a protein obtained or derived from *Capillaria hepatica* or *Dicrocoelium dendriticum*, as recited in amended Claim 1. Further, amended Claim 1 recites: *wherein said helminth-based antigen increases said mammal's blood serum levels of Immunoglobulin E levels (IgE) to greater than about 3,000 IU/ml thereby ameliorating the allergic reaction of said mammal to a plurality of antigens.* There is simply no teaching, suggestion, or motivation in the cited art to use a helminth-based antigen that increases IgE levels in order to treat allergies or asthma.

Accordingly, Claim 1 is patentable over the cited art. The claims which depend from Claim 1 are also allowable because they depend from an allowable base claim and/or because they recite independently patentable features. Thus, Applicant respectfully requests that the Examiner withdraw the rejection under 35 U.S.C. § 102(b).

¹ Any argument regarding the cited art should not be construed as an admission that the art qualifies as prior art.

Appl. No. : 10/719,532
Filed : November 21, 2003

Claim Rejections Under 35 U.S.C. § 102(b): Rejection Over Gonzalez-Lanza et al.

The Examiner rejected Claims 1-6 and 11-12 under 35 U.S.C. § 102(b) as being anticipated by *Gonzalez-Lanza et al.*

As amended, Claim 1 recites: *wherein said helminth-based antigen increases said mammal's blood serum levels of Immunoglobulin E levels (IgE) to greater than about 3,000 IU/ml thereby ameliorating the allergic reaction of said mammal to a plurality of antigens.* There is simply no teaching, suggestion, or motivation in *Gonzalez-Lanza et al.* to use a helminth-based antigen that increases IgE levels as recited in amended Claim 1 in order to treat allergies or asthma.

Accordingly, Claim 1 is patentable over *Gonzalez-Lanza et al.* The claims which depend from Claim 1 are also allowable because they depend from an allowable base claim and/or because they recite independently patentable features. Thus, Applicant respectfully requests that the Examiner withdraw the rejection under 35 U.S.C. § 102(b).

Claim Rejections Under 35 U.S.C. § 102(a)

The Examiner rejected Claims 1-5, 8 and 11-12 under 35 U.S.C. § 102(a) as being anticipated by U.S. Patent 6,207,158.

Claim 6 stands unrejected over U.S. Patent 6,207,158. Applicant has amended Claim 1 to recite the elements of Claim 6. Therefore, the cited art does not anticipate Claim 1, as amended.

Moreover, U.S. Patent 6,207,158 fails to render obvious Claim 1. The cited art fails to teach or suggest the use of a helminth-based antigen that increases said mammal's blood serum levels of Immunoglobulin E levels (IgE) to greater than about 3,000 IU/ml thereby ameliorating the allergic reaction of said mammal to a plurality of antigens.

Accordingly, Claim 1 is patentable over U.S. Patent 6,207,158. The claims which depend from Claim 1 are also allowable because they depend from an allowable base claim and/or because they recite independently patentable features. Thus, Applicant respectfully requests that the Examiner withdraw the rejection under 35 U.S.C. § 102(a).

Appl. No. : 10/719,532
Filed : November 21, 2003

Reservation of Rights

Claims canceled in this application are done so without prejudice. Moreover, although the present communication may include alterations to the application or claims, Applicant is not conceding that the previously pending claims are not patentable over the art of record. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserve the right to later pursue any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Appl. No. : 10/719,532
Filed : November 21, 2003

If any matters should remain, the Examiner is invited to contact the undersigned at the telephone number provided below. No fees are believed due. However, please charge any fees, including any fees for additional extensions of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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